

REMARKS

The Examiner has acknowledged Applicant's election with traverse of Group II, Claims 15-19. However, the Examiner has deemed the restriction requirement proper and states that in her comments it is final. Applicant's note that on the cover sheet of the office action the Examiner indicates that Claims 1-46 are pending and that Claims 15-19 stand rejected but makes no further reference to Claims 1-14 and 20-46 on the cover sheet. Applicants maintain their traverse of the restriction requirements, but in view of the fact that the Examiner has directed her review and comments to Claims 15-19, Applicants will respond at this time to the Examiner's comments regarding Claims 15-19.

Rejection under 35 U.S.C § 112.

The Examiner has rejected Claim 15 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Specifically, the Examiner asserts that the phrase "a particular entity" in line one is vague and indefinite.

Applicants respectfully direct the Examiner to the text of Claim 15 which limits the "particular entity" to a component that (1) induces a known biological effect and (2) requires that the biological effect is limited to effects that induce a detectable change in the second domain of the fusion protein. The skilled person designing assay protocols can easily tell whether he is dealing with an analyte which has those specific characteristics. Further please note that the first

domain as stated in Claim 15 is a phycobiliprotein domain. Thus, the second domain is distinguished from the phycobiliprotein domain of the fusion protein.

Consequently, the skilled person would not find the claim vague or indefinite and Applicants respectfully submit that the term is defined and is not vague. Accordingly, Applicants request that the Examiner withdraw her rejection of Claim 15 under 35 U.S.C. § 112, second paragraph.

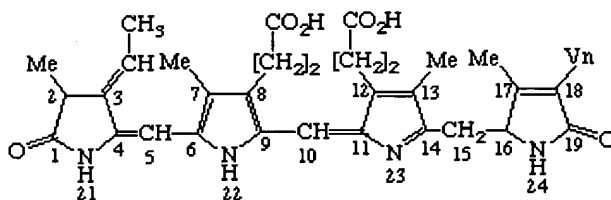
Rejection Under 35 U.S.C. § 103

The Examiner has rejected Claims 15-19 under 35 U.S.C. 103 (a) as assertedly unpatentable over Schluchter et al. (Journal of Biological Chemistry, Vol. 272, No. 21, Issue May 23 (13562-13569) in view of Stryer et al. (U.S. Patent No. 4,859,582).

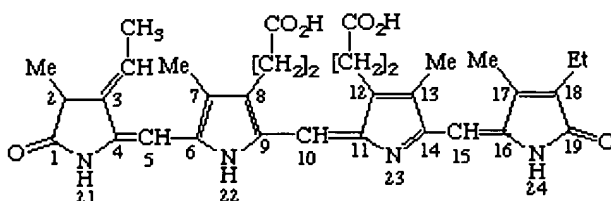
Applicants respectfully submit that Claims 15-19 are drawn to assay methods which make use of fusion proteins. Dorland's Illustrated Medical Dictionary, published by W.B. Saunders, Harcourt Health Sciences, defines **fusion protein**, as "a protein produced by a recombinant DNA construct engineered such that the coding region of one gene is linked distal to the 5' end of another gene and within its coding region, placing expression of both genes under regulatory control of the second, usually well characterized, gene."

The Office Action erroneously refers to "fusion proteins such as phycocyanobilin, phytochromobilin and phycoerythrobilin, which are all phycobiliproteins that contain protein domains." Office Action, page 3. Contrary to the assertion in the Office Action, phycocyanobilin, phytochromobilin and phycoerythrobilin are linear tetrapyrrole prosthetic

groups that are covalently bound to phycobiliprotein apoproteins to produce phycobiliprotein holoproteins. Structure for phycoerythrobilin and phycocyanobilin are provided below:



Phycoerythrobilin



Phycocyanobilin

Further, Schluchter is directed to enzymatic steps in the pathway for synthesis of tetrapyrrole prosthetic groups, which *in vivo* may eventually be incorporated into phycobiliproteins. Stryer is directed to assays with detection systems using phycobiliproteins isolated from algal cells as fluorescent moieties. Neither reference deals with fusion proteins, and it is unclear in the first instance how the skilled person would be induced to try to combine the studies of Schluchter regarding biosynthetic pathways with Stryer's modification of binding assay protocols, and in the second instance what result the skilled person would possibly expect to achieve by such combination. For at least these reasons Schluchter in view of Stryer does not teach or suggest the Applicants' invention.

Furthermore, the assays disclosed by Stryer are binding assays, not enzyme activity assays. Nothing in the Office Action provides any reason why the skilled worker would be motivated to refer to Stryer's description of binding assays for modification of enzymatic assays involving phosphokinase, protease or ribozymes. Clearly such enzymes are not involved in the pathways studied by Schluchter, so there is no prima facie case of obviousness for claims 17-19.

For the reasons discussed above in detail Applicants submit that Schluchter in view of Stryer does not render Claim 15 and Claims 16-19 which depend from Claim 15 obvious under 35 U.S.C. 103 (a). Applicants respectfully request that the Examiner withdraw her rejection of Claims 15-19.

CONCLUSION


For at least the reasons set forth above, Applicants respectfully submit that claims 15-19 are in condition for allowance. Applicants therefore request that the claims be allowed.

It is believed that no fees other than the extension of time fee is due with this response. However, if any additional fees are determined to be due, the Director is hereby authorized to charge these fees to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

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